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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/300,482	04/28/1999	NORDINE CHEIKH	04983.0031.U	4511

28381 7590 12/22/2005

ARNOLD & PORTER LLP
ATTN: IP DOCKETING DEPT.
555 TWELFTH STREET, N.W.
WASHINGTON, DC 20004-1206

EXAMINER	
MORAN, MARJORIE A	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 12/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/300,482	CHEIKH ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11-13,15-22,24 and 27-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 11-13, 15-22, 24, and 27-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1, 11-13, 15-22, 24, and 27-31 are pending.

Claim Objections

Claims 27 and 29 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 27 and 29 depend, respectively, from claims 26 and 10, which are cancelled. In the response filed 9/26/05, applicant argues that this objection should be withdrawn as claims 27 and 29 are cancelled. The claims were not cancelled in the amendment of 9/26/05, filing concurrently with the arguments, or in any subsequent amendment, therefore the objection is maintained.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 11-13, 15-22, 24, and 27-31 are again rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility. The arguments filed 9/26/05 have been fully considered but are not persuasive.

The examiner aggress that the "threshold for utility is not high", but maintains that in the absence of a well-established utility, the instant specification must disclose a utility for the *claimed subject matter* which is specific, substantial and useful. See MPEP 2107.

Applicant's arguments with regard to uses of the claimed nucleic acids to identify polymorphisms, or to determine a level or pattern of expression, as set forth on pages 8-9 of

the response, are not persuasive as these are generic uses applicable to the broad class of nucleic acids, and are not specific to the particular sequences recited in the instant claims. None of the recited sequences are disclosed as comprising a polymorphic site, nor are any of the claimed sequences disclosed as being differentially expressed in a particular tissue or at a particular stage of development such that the sequences may be used to identify of distinguish that tissue or developmental stage, or to identify or distinguish a disorder or disease associated with the tissue or developmental stage. Applicant is reminded that a "use" to perform further research (e.g. to identify a polymorphism, which THEN may be correlated to a specific phenotype) is not a utility under 35 USC 101.

As set forth in previous office actions, where a nucleic acid does not, in itself, have a utility, utility maybe established based on a polypeptide encoded. The instantly claimed nucleic acids are not disclosed to be promoters, etc. which would, pre se, have utility, thus examination of the claims is, as previously, carried out based on utility with regard to putatively encoded polypeptides. In response to the repeated argument that the claimed sequences encode phosphogluconate pathway enzymes, it is again noted and maintained that the specification does not actually disclose that any of the claimed SEQ ID NO's is known to encode a protein or peptide, specifically one of the enzymes recited in the claims. For the nucleic acid to have utility based on a putatively encoded peptide, the identity and activity of the peptide must be known or established. Contrary to applicant's arguments, the specification does not, in fact, disclose ANY amino acid sequences, specifically ones encoded by the claimed nucleic acids. The only "evidence" supporting applicant's argument that the claimed nucleic acids encode enzymes is set forth in the instant specification is found in Table A, pages 224-242. Table A discloses, for example, that SEQ ID NO: 1 is PREDICTED to encode a polypeptide with 58% homology to a dehydrogenase. Using "sound scientific reasoning" and absent any information with regard to

homology between conserved regions, catalytic domains, etc., one skilled in the art of either molecular biology or biochemistry would reasonably doubt that a PUTATIVELY encoded polypeptide would, in fact, have the same activity as a protein to which it exhibits only 58% homology.

In response to the argument that the claims also recite "fragments", thus a complete ORF is not necessary, it is again noted that a fragment of a protein, wherein the fragment itself does not have utility or activity, does not necessarily have a utility.

Also contrary to applicant's arguments, the examiner has NOT stated that an ORF or knowledge of an appropriate ATG codon is necessary. However, where the utility of a nucleic acid sequence rests on the utility of an encoded protein, knowledge of an ORF or appropriate ATG would *be helpful* to one skilled in the art to determine what, if any peptide may be expressed by a particular nucleic acid sequence. In fact, as previously set forth, and despite applicant's arguments to the contrary, it is not known for ANY of the claimed sequences what the ORF is, or whether any sequence is actually translated into a peptide, or, if translated, what the activity or function of that peptide may be. For example, SEQ ID NO: 14 comprises six "ATG" codons, but it is not known which, if any, is the start codon for a 6-phosphogluconate dehydrogenase. As set forth in the office action of 12/20/00, none of the claimed SEQ ID NO's appears to be long enough to encode the entirety of the enzyme disclosed by the specification to be putatively encoded thereby. It is possible that a claimed SEQ ID NO: encodes a fragment of an enzyme; however, it is not disclosed anywhere whether an encoded *fragment* of a polypeptide has activity or another function such that the fragment has utility under 35 USC 101. In response to the argument that fragments may be used as probes, it is noted that a "probe" (i.e. for a homologous sequence) for a sequence of unknown function does not impute utility to the probe itself. There is no evidence in the instant specification, and none has been

filed to show or support that any of the claimed nucleic acids do, in fact, encode ANY peptide, specifically one with enzymatic activity. To reiterate from the previous office action, and in response to the argument that the examiner has "admitted" that the specification discloses that the nucleic acids encode enzymes, it is noted that the totality of the examiner's statements indicate that while Table A indicates a relationship between the claimed sequences and enzymes known in the art, the specification does not, in fact, teach that the claimed nucleic acid sequences are known to actually encode ANY protein or peptide, specifically those set forth in Table A.

In response to the argument that the claims do not recite enzymes, it is noted that claims 1 and 24 do, in fact, recite nucleic acids which encode enzymes. The examiner agrees with applicant that the claims are directed to nucleic acids. It is again noted that a nucleic acid may have utility if it encodes a polypeptide with either a well-established or a specific, substantial and credible utility. Enzymes with a known activity are generally regarded as having a well-established utility. Thus, the instantly claimed nucleic acids MAY have utility if they do, in fact, encode enzymes; hence the analysis of the claims with regard to encoded enzymes. However, the specification does not disclose, and no evidence has been filed, to establish that the claimed nucleic acids, in fact, encode enzymes or any other polypeptide with a known activity or identity such that a utility may be ascribed to the encoding nucleic acids.

For all the reasons previously set forth and set forth above, the rejection is maintained.

Claims 1, 11-13, 15-22, 24, and 27-31 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above, one skilled in the

art would not know how to use the claimed invention. As the utility rejection is maintained, so is the enablement rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 22, 24 and 28 are again rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a LACK OF ENABLEMENT rejection.

Applicant's arguments filed 9/26/05 have been fully considered, but are not persuasive. In response to the argument that the examiner "alleges" that the claims are addressed to enzymes, it is noted, as set forth above, that the examiner agrees that the claims are directed to nucleic acids. However, claims 1, 22, 24, and 28 explicitly limit the nucleic acids to be ones which encode particular enzymes. The instant specification does not teach that the claimed nucleic acids are known to encode polypeptides with enzymatic activity. Also as set forth above, none of the claimed nucleic acids appears to be long enough to encode the entirety of any of the enzymes recited in the claims. Further, it is not known whether any encoded fragment of a polypeptide would have enzymatic activity. The instant specification does not disclose any comparison of conserved regions, catalytic domains, etc., between known enzymes and putatively encode peptides such that one skilled in the art would be able to determine whether the instantly claimed polynucleotides actually encode polypeptides with

enzymatic activity. In response to the argument that the ORFs are not required for enablement, it is noted that the examiner stated that ORFs would be *helpful* in determining whether a claimed polynucleotide does, in fact, encode a recited enzyme, or any fragment thereof. However, even knowledge of an ORF may not be sufficient to determine whether a polynucleotide does indeed encode a polypeptide with the recited enzymatic activity. Contrary to applicant's argument on page 14 of the response, the instant specification does not disclose amino acid sequences anywhere. For these reasons and those previously set forth, the examiner maintains that one of skill in the art would not know how "to use" the claimed nucleic acids to encode an enzyme, as claimed.

35 U.S.C. 112, Written Description Rejection

Claims 1, 22, 24, and 28 are again rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's arguments with regard to claims 11-13, 15-21, 27 and 29-30 are persuasive, therefore the rejection under 35 USC 112 for lack of written description is hereby withdrawn with regard to claims 11-13, 15-21, 27 and 29-30. Applicant's arguments filed 9/26/05 for claims 1, 22, 24, and 28 have been fully considered but they are not persuasive. Applicant's arguments are addressed below.

The specification discloses SEQ ID NO's 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619. which putatively encode various phosphogluconate pathway enzymes. Claims 1, 22, 24 and 28 are specifically directed to encompass sequences that encode a variety of enzymes. As the sequences recited in the claims are apparently fragments which do not appear to comprise

ORF's or actually encode any known proteins, a nucleic acid "comprising" the fragments encompasses much larger sequences which may encode entirely different proteins with entirely different activities from those of the recited enzymes.

Applicant argues the disclosure need only show that applicant was in possession of the claimed inventions, and insists that the instant specification does so. In response, it is noted that the specification does not, in fact, actually describe any nucleic acid KNOWN to encode an entire enzyme, and therefore does not describe nor show possession of the claimed invention of at least claims 1, 22, 24, and 28.

For all of the reasons set forth above and previously set forth, the rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 11, 16, 29, and 31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/425,114. Although the conflicting claims are not identical, they are not

patentably distinct from each other because SEQ ID NO: 28,690 of '114 is identical to instant SEQ ID NO: 225, therefore claim 1 of '114 encompasses the subject matter of each of claims 1, 11, 16, 29, and 31.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 11, 16, 29, and 31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/425,115. Although the conflicting claims are not identical, they are not patentably distinct from each other because SEQ ID NO: 155,395 of '115 is identical to instant SEQ ID NO: 225, therefore claim 1 of '115 encompasses the subject matter of each of claims 1, 11, 16, 29, and 31.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant has stated in the response filed 9/26/05 that upon an indication of allowable subject matter, a terminal disclaimer will be filed, and requests withdrawal of the rejection. A terminal disclaimer has not been filed. Applicant has not amended either the instant claims nor those of the copending applications to overcome this rejection and the rejection may not be held in abeyance, therefore it is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon,Wed: 7-1:30; Tue,Thur: 7:30-6; Fri 7-3:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
12/12/05